

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/470,489	06/06/95	MONTAGNIER	L 2356.0014-09

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EXAMINER

PARKIN, J

ART UNIT

1648

PAPER NUMBER

DATE MAILED: 04/29/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/470,489	Applicant(s) Montagnier et al.
	Examiner Jeffrey S. Parkin, Ph.D.	Group Art Unit 1648

Responsive to communication(s) filed on 9 Jan 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 72-89 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 72-89 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 17

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of the amendment filed 09 January, 1998, wherein claims 42-49, 52-59, and 62-71 were canceled without prejudice or disclaimer and new claims 72-89 submitted. Claims 72-89 are pending in the application.

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35 U.S.C. § 112, First Paragraph

2. The previous rejection of claims 42-49, 52-59, and 62-71 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is moot in view of applicants' response.

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3. The previous rejection of claims 42-49, 52-59, and 62-71 under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, is moot in view of applicants' response.

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Non-statutory Double Patenting

4. The previous provisional rejection of claims 42, 49, 52, 59, 62, and 69 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 83 of copending application Serial No. 08/250,103, is moot in view of applicants' response.

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New Grounds of Rejection

35 U.S.C. § 112, Second Paragraph

5. Newly submitted claims 72-89 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims refer to "hybridization conditions of T_m -42°C, T_m -20°C, and T_m -3°C [sic- T_m]" which is vague and confusing. The melting temperature (T_m) is defined as the temperature when half the duplex molecules (i.e., single-stranded probe bound to target) have dissociated into their constitutive single strands. However, merely citing a T_m fails to provide any illumination pertaining to the precise hybridization conditions that should be employed. A number of factors affect the T_m of any given hybridization reaction including the monovalent cation concentration, the base composition expressed as a mole fraction of G and C residues, the length in nucleotides of the shortest chain in the duplex (L), and the concentration of helix-destabilizing agents such as formamide (Wahl et al., 1987; Wallace et al., 1987; Ausubel, 1987). The stringency of any given reaction can be altered by adjusting the salt concentration and/or formamide concentration and/or temperature. The stringency can be adjusted during the hybridization or posthybridization wash. Therefore, it is imperative that the hybridization conditions are accurately disclosed. Applicants are referred to pages 17, 32, and 54 of the specification wherein precise hybridization conditions are disclosed (e.g., the hybridization reaction was carried out at 42°C in the presence of 50% formamide, 0.1% SDS, and 5X SSC for 18 hours and

washing steps were carried out at 50°C in the presence of 0.1% SDS and 2X SSC). Applicants may obviate the rejection by incorporating those specific parameters, as supported by the disclosure, into the claim language (i.e., A method of detecting HIV-2 in a biological sample comprising the following steps: a) preparing a labeled HIV-2-specific probe having the following sequence . . .; b) hybridizing the labeled probe of step a) with a sample of interest under conditions that promote the formation of nucleic acid duplexes wherein said conditions are stringent and comprise a hybridization temperature of 42°C in the presence of 50% formamide, 0.1% SDS, and 5X SSC for 18 hours; c) removing nonspecifically bound probe by washing the sample at a temperature of 50°C in the presence of 0.1% SDS and 2X SSC; and, d) detecting the formation of duplexes.).

The claims also refer to nucleic acid molecules that "hybridize to a greater extent" to HIV-2 than HIV-1. It is not readily manifest how the skilled artisan could measure the recited properties absent a description of the specific parameters involved in making any comparisons. Applicants may obviate this rejection by amending the claim language to recite an "an HIV-2-specific probe."

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35 U.S.C. § 112, First Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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35 7. Newly submitted claims 72-89 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Claims 72-79, 88, and 89

are drawn toward methods of detecting HIV-2 employing nucleic acid probes under conditions providing the recited T_m . Claims 80-89 are drawn toward methods of producing hybridization probes under conditions having the recited T_m . The disclosure provides a number 5 of molecular clones containing HIV-2 cDNA fragments (refer to pages 23, 25, 26, 28, 37, and 62). Specifically, the following clones were described: E2, 27-5, 4.8, 35, and 4.7. Appropriately drafted claim language directed toward these fragments would be allowable.

However, the broadly recited claim language is presently directed 10 toward any nucleic acid capable of hybridizing to HIV-2 genomic RNA or DNA. Accordingly, the claim language encompasses millions of possibilities. However, the disclosure only provides limited guidance pertaining to nucleic acids that may prove suitable as such probes. Applicants submit that the disclosure provides adequate 15 guidance for the skilled artisan to determine, without undue experimentation, which probes will possess the desired properties. Applicants' arguments have been thoroughly considered but are not deemed persuasive for the reasons of record in Paper nos. 5, 9, 16, and as further enumerated below.

Applicants' disclosure only details the preparation of a limited 20 number of cDNA clones. While HIV-2-specific probes may be generated from these clones, the claim language encompasses a much larger genus of molecules for which there is inadequate support. Applicants have clearly not met their burden under the first paragraph pertaining to 25 an adequate written description of those nucleotide probes that can reasonably be expected to function in the recited manner. When all of the aforementioned issues are considered *in toto*, it would clearly require undue experimentation the skilled artisan to ascertain all the scientific parameters required to practice the instantly claimed 30 invention. Applicants may obviate this rejection by directing the claim language toward the aforementioned HIV-2 cDNA clones.

Finality of Office Action

8. Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

5 **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

Correspondence

10 9. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

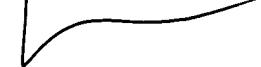
15 10. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

20 35 11. Any inquiry concerning this communication should be directed to **Jeffrey S. Parkin, Ph.D.**, whose telephone number is **(703) 308-2227**. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Donald E. Adams, Ph.D.**, can be reached at (703) 308-0570. Any inquiry of a general nature or relating to the

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status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

23 April, 1998

DE Adams
DONALD E. ADAMS
SUPERVISORY PATENT EXAMINER